UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

UNIMED PHARMACEUTICALS, INC., a Delaware Corporation, and LABORATORIES BESINS ISCOVESCO, a Delaware Corporation, Plaintiffs, v. PADDOCK LABORATORIES, INC., a Minnesota Corporation, Defendant.	**Civil Action No.** **File No. 1:03-CV-2503-TWT**

PADDOCK'S REPLY BRIEF IN FURTHER SUPPORT OF ITS MOTION *IN LIMINE* TO EXCLUDE UNIMED'S ARGUMENT AND EXPERT TESTIMONY ON THE BASIS OF, AND SUPPORT IN THE SPECIFICATION FOR, THE SODIUM HYDROXIDE RANGES RECITED IN CERTAIN CLAIMS OF THE '894 PATENT

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I. Contrary To Unimed's Straw-Man Contentions, Paddock's Present Motion Does Not Challenge The Assertion Of the Attorney-Client Privilege, Is Not A Discovery Motion, Does Not Advance The Proposition That The Mere Assertion Of The Privilege Justifies Excluding Evidence And Does Not Rest On A Negative Inference Based Merely On Unimed's Assertion Of The Privilege

In opposing Paddock's motion in limine to preclude Unimed from proffering arguments and expert testimony relating to the basis, if any, and support, if any, in the specification, for the ranges of sodium hydroxide recited in the claims of the '894 patent, Unimed spends a great deal of time addressing arguments that Paddock did not make while mischaracterizing the essential thrust of Paddock's argument and the peculiar facts presented here on which it is based. As further explained below, by this motion Paddock does not seek to compel discovery, to sanction discovery conduct, or to create some new legal principle. Instead, Paddock contends that the unique fact pattern presented here and its relationship to the legal issues that arise from it makes preclusion of such arguments and evidence appropriate and fair in order to avoid unfair prejudice to Paddock.

Paddock concedes that its moving brief does not cite a case on all fours with the present one; however, neither does Unimed's opposition brief – Unimed has cited a number of cases for propositions that are not in contention on this motion. The cases cited by Paddock while generally dealing with the sword/shield prohibition in asserting the attorney-client privilege, also speak to the Court's

ability to craft appropriate evidentiary remedies when one party's assertion of the attorney-client privilege is unfairly prejudicial to the adverse party.

Unimed spends pages defending its assertion of the attorney-client privilege, but Paddock did not and is not contesting Unimed's assertion of the attorney-client privilege with respect to the relevant portions of Paddock's depositions of the two fact witnesses in question, i.e., Dr. Dudley, the named inventor who supervised the prosecution of the patent and served as the president of Unimed during much of the relevant period, and Mr. Mahoney, the patent attorney who prosecuted the '894 patent.

Contrary to Unimed, Paddock's motion in limine plainly is not a belated discovery motion. Paddock does not seek to compel discovery, nor does it seek a "sanction", as Unimed suggests, for an alleged failure to provide discovery.

Also contrary to Unimed, Paddock is not advancing the straw-man proposition that the "mere assertion" of the attorney-client privilege alone justifies the exclusion of potentially or arguably relevant evidence at trial.

Finally, Paddock does assert that "inconvenient facts" are being cloaked by the invocation of the privilege. But this assertion does not rest, as Unimed says, on an adverse inference being drawn based on Unimed's assertion of the privilege. It arises instead from what the record, particularly the intrinsic evidence of the patent

(including its prosecution history) shows. For the reasons set forth in Paddock's briefing on claim construction and in its two pending summary judgment motions, the intrinsic record of the patent shows that the sodium hydroxide ranges recited in the claims were, among other things, belatedly added to the claims with no basis or support in the application as originally filed, were fatally botched, and that the insertion of 0.1 N into those claims by the Certificate of Correction is not valid and cannot cure the legal defectiveness of those claims.

II. Paddock's Request For Relief Is Narrowly Based On The Unique Fact Pattern Presented And The Legal Issues That Arise From It

Rather than asserting any of these straw-man contentions, as Unimed's opposition would have the Court believe, Paddock's instant motion rests on the contention that on the unique facts presented here, Unimed, having chosen to assert the attorney client privilege to block discovery on this important issue from the only two persons with first hand knowledge (of any alleged basis for the sodium hydroxide ranges belatedly inserted into the claims in the patent) should, in order to prevent unfair prejudice to Paddock, be precluded from offering (as it turns out, reams and reams) of expert testimony and attorney argument on that precise issue.

The following summarizes the key, highly case specific facts that gave rise to this motion. These facts are discussed at length in the moving briefs in support of Paddock's motions for invalidity of the Certificate of Correction and for the

invalidity of claims 1-30 as lacking a written description as required by 35 U.S.C. § 112.

As originally filed, the patent application that resulted in the '894 patent contained no reference to sodium hydroxide whatsoever, other than the precise amount listed for that ingredient in the Androgel formulation, as listed in Table 5 of the patent. None of the original claims specifically recited sodium hydroxide as an ingredient and, therefore, certainly none of the original claims recited a range of amounts of sodium hydroxide.

Only much later, during the prosecution of the patent, did Unimed amend the claims to recite the ranges that appear in the claims as issued. That amendment was accompanied by a conversion calculation, offered in support of the amendment, that purported to convert the amount of sodium hydroxide (in solution) in the Androgel formulation to the equivalent amount of pure (solid) sodium hydroxide. The result of that calculation (1.8%), which was off by a factor of 100, was evidently used as the basis around which were constructed the ranges for sodium hydroxide (1-3% and 1-5%) then being added to the claims by amendment.

Much later still, after the patent had issued, Unimed obtained a Certificate of Correction that amended the claim language relating to the recited sodium

hydroxide range by adding the modifier "O.1 N" (indicating a certain highly dilute concentration) to the term sodium hydroxide.

Unimed does not dispute that the only two fact witnesses with first hand knowledge of how and why the claims were amended during prosecution to add the sodium hydroxide ranges are Dr. Dudley and Mr. Mahoney, who we are told can provide no fact testimony on this issue because its privileged. Significantly, then, because discovery from Dr. Dudley and Mr. Mahoney was blocked by Unimed's assertion of the privilege, other than the erroneous conversion calculation, there is simply nothing in the record (putting aside the speculations of Unimed's experts) that sheds any light on the origin or basis of the sodium hydroxide ranges that were added to the claims by this amendment.

The issues of what the sodium hydroxide clauses in the claims as issued means, and on what basis the ranges for that ingredient were added to the claims, are of course of signal importance in this case because, as the pending claim construction issues and motions for summary judgment clearly illustrate, dispositive legal issues hang on the construction and validity of precisely the claims containing the sodium hydroxide range limitations. Unimed seeks to minimize the significance of the actual facts underlying the insertion of these ranges into the claims, contending that it is more appropriately addressed by expert

testimony as to what one of ordinary skill would understand from reading the application. However, given the facts presented by this prosecution history, it is plain that having information as to what the actual, not supposed, hypothetical or speculative or presumed basis was for the insertion of the ranges in the claim and the role of the conversion calculation in constructing those ranges is absolutely relevant and, on the highly unusual fact pattern presented here, dispositive.

Thus, we have a situation where there is a crucial claim limitation in issue, a limitation which was added during prosecution having no express basis in the specification; a claim limitation, an important feature or element of the claimed invention, as to which in effect there can be no fact discovery (by way of deposing a fact witness) because of the patentee's assertion of the attorney client privilege. This, in circumstances where it is clear that the patentee's position on the support for or basis for this claim limitation, as supported by attorney argument and the speculations of plaintiffs' experts, is either manifestly a sham or, at the very least, highly suspect on its face. Thus, Unimed has used its ability to assert the privilege to hide from examination the factual basis for and origin of a highly important parameter or limitation of the claimed invention.

It is, then, in these unique circumstances that Paddock contends that Unimed's election to assert the privilege – which has the effect of blocking all

pertinent fact discovery from the only fact witnesses with first hand knowledge – works an undue and unfair prejudice on Paddock; a prejudice which can only be fully and fairly redressed by precluding Unimed from filing this factual gap with attorney argument and expert speculations.

Dated: January 31, 2006

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 31, 2006, a true and correct copy of the foregoing document was filed electronically via CM/ECF in the United States District Court for the Northern District of Georgia, with notice of same being electronically served by the Court, addressed to:

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This 31st day of January, 2006.

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